UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 C.A. No.: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris

WATSON PHARMACEUTICALS, INC.'S RESPONSE TO CLASS PLAINTIFFS' RESPONSE TO AMGEN AND WATSON'S SUPPLEMENTAL OPPOSITION TO CLASS CERTIFICATION

Exhibit 6: Medicare Payments for Currently Covered Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 107th Cong. 10 (2002) (statement of the Hon. Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services).

MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

THURSDAY, OCTOBER 3, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:38 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

The Medicare program is broken. Physicians are declining to see Medicare patients because of low reimbursement rates, reimbursement for new technologies used in outpatient settings is scheduled to be severely cut, and seniors in Minnesota pay higher premiums and receive fewer benefits than seniors in many other states under the Medicare+Choice program.

The biggest factor driving all of these issues is the arbitrary formulas used in the Medicare program to determine reimbursement rates. Medicare reimbursement must be reformed to reflect real world market transactions.

At the same time, we must make sure that new approaches to reimburse based on actual costs are accurate and truly encompass all costs associated with the medical procedure. Reimbursement for medical devices used in outpatient care is a perfect example of the inability of our system to accurately capture and report actual costs associated with medical services.

For example, the proposed 2003 rule for the outpatient prospective payment system is based on nearly 60 million hospital claims. One would assume these claims provide an accurate view of the costs associated with performing a medical procedure. Unfortunately, further review of the hospital claims shows significant flaws in the hospital coding process. For example, these claims, which served as the basis for 2003 payment rates, included submissions showing cardioverter-defibrillators used in colonoscopies and carpal tunnel surgeries and pacemakers used in cataract surgeries. In fact, of the 3,322 single-procedure claims for pacemaker insertions reviewed, 50 percent of those claims were coded incorrectly.

Madam Chairwoman, Medicare's reimbursement policies must be reformed to reflect costs, and these costs must be accurate. Medicare's ability to accurately reimburse for Medicare services may be the biggest determinant of what medical services are available to our seniors. These aren't just reimbursement formulas or proposed rules—these may be life or death decisions for millions of elderly Americans.

Thank you, Madam Chairwoman, for holding this hearing, and I look forward to working with you to ensuring that seniors have access to the health care they need and deserve.

Chairman JOHNSON. Mr. Scully?

STATEMENT OF THE HON. THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Mr. SCULLY. Madam Chairwoman, Congressman Stark, and Members of the Subcommittee, thank you for having me here today. I am always happy to be here on an issue I think we have so much agreement on.

Obviously, as I think we all know, we all wanted to be talking about larger Medicare prescription drug issues this year. We still hope to get a Medicare drug benefit out of Congress this year. That seems increasingly unlikely. From the Administration's point of view, we would like to congratulate you for getting a Medicare prescription drug bill out of the Committee and out of the House. We certainly are committed to getting that legislation passed as soon as we can.

Back to AWP, this is a longstanding problem. Medicare pays about $5 billion a year for about 450 outpatient drugs. We pay far more than any of the purchasers of these drugs, and the agency has been determined for many years to try to find a way to fix it.

This is the third time I have testified on AWP this year. Having testified on a lot of issues, I can tell you that rarely have I seen the kind of bipartisan support for fixing a problem that this issue has. Senator Baucus and Senator Grassley in the Senate Committee on Finance were both very supportive of fixing this problem. Chairman Tauzin and Congressman Dingell were literally jumping up and down in their hearing to fix this problem. The Administration is very anxious to work with all of Congress, including this Committee, to fix this problem.

I think this is clearly one place where Congress has a very huge problem that needs to be fixed. There are a number of ways to fix AWP. We support a lot of what the Committee has been talking about in your proposal on competitive bidding. We think that is one approach that could easily work. Mr. Stark's approach is another. The House Committee on Commerce, as you probably know, proposed using the average sales price (ASP), which is similar to Mr. Stark's bill. I think we have been saying all year long, we may have opinions. We would work with any one of them. The one thing that is clear is we are overpaying for all these drugs.

Just to give you one example on the competitive bidding front, which we think in the long range—in the short range, an ASP approach or picking a new and better AWP may be the short-term fix. We believe, however, that even those numbers potentially could be gamed in the long run, as AWP has been. In the longer term, we think a more market-oriented approach may work.

Just to point out one example, in San Antonio last year in our DME competitive bidding proposal, we put out a bid for Albuterol, a widely used drug for asthmatics, and we received 30 bids. Eleven companies out of the 30 were accepted. We saw a 25-percent reduction in the price that we paid. It worked out to about average wholesale price minus 30, not average wholesale price minus 5. Not every drug is that easy to compete with. San Antonio is a big town. We understand competitive bidding may have other issues in smaller markets. It is very clear that we are overpaying and not paying market prices for drugs.

We are also very concerned, as you are. We have said to the oncologists and others, that there are a number of areas—particularly, oncology, hematology, and dialysis facilities—where providers rely on the cross-subsidy from high average wholesale prices for drugs to make up for what they perceive, in some cases probably correctly, to be an underpayment for their basic services. We think on any proposal to fix AWP needs to address that.

The GAO report, that came out earlier said that they believe that the oncology practice expense payments were underpaid by about $49 million. An earlier CMS report suggested that number was $52 million. We have been spending a lot of time with the oncologists, and it is part of our ongoing rulemaking. I cannot get into the details they submitted, but it is significantly higher, which probably is not surprising given the number. We do think that we need to find the right amount for practice expenses. As we reduce the overpayments for AWP, that we need to make adjustments probably, at the very least, for oncologists, hematologists, and for dialysis facilities.

There are problems here. This fits into a broader payment concern. We believe the easiest way to fix this is for Congress to fix it, because if you fix it and we get the savings through average wholesale price, you can redistribute the appropriate money back into the base to pay oncology fees. It is very unclear at this point whether the agency has the ability to do that administratively.

Our concern is we could save, we could discuss any number, say $100 million a year to $1 billion a year on overpayment for AWP. We have looked at legally whether we could actually save the money administratively and put it back in the payment rates. It is

not clear. It is not clear that we cannot, but it is also not clear that we can. It would clearly be much cleaner to take the savings and for Congress to put the money back in the program.

If we cannot put it back in administratively, you can see the potential problem we have. If we were to add, let us say hypothetically, $100 million a year back for the oncologists, we are in a context, at least right now, which we also hope to fix, where we are looking at a physician update of negative 4.4 percent on the base conversion factor next year—an outcome I think all of us are hoping to avoid in the next few weeks for which the Administration strongly supports technical fixes.

In the context of fixing payments to oncologists, if in the current setting we had to put $100 million back into the base for oncology fees as we fix the AWP, that update would not be negative 4.4 percent, it would be negative 4.6 percent. So, the idea in a budget neutral sense of fixing the oncology practice expenses as you save money in AWP is probably not particularly appetizing for anyone, including the oncologists. So it may be an option, but it is not clear that we can do that legally. That is one of the major reasons all year long we supported the idea of Congress making this fix and telling us, at least directing us, even if it is in somewhat vague terms, to make the market-base fix and to put some of the money back into the appropriate practice areas.

There are a number of impacts of AWP that I do not think a lot of people understand. We clearly way overpay for drugs, but I want to go through one example because I think while we overpay for drugs. It is obviously a huge problem for taxpayers if we are overpaying $1 billion a year on drugs, which some folks claimed, but it also has an impact all through the rest of the health care system. So, I brought some charts today to illustrate that.

About 80 percent of these drugs are paid for in physicians' offices, but about 20 percent are paid for in hospital outpatient settings. As you know, right now we are going through a rewrite of our hospital outpatient rule, which is incredibly complicated. I am spending a great amount of time on. Last year, we paid most of what are called pass-through drugs at 95 percent of AWP, and when we pay that, we significantly overpaid for a lot of drugs.

This year, in our draft rule, we used about 60 million claims to figure out the real rate that hospitals paid for drugs. Those rates came down significantly, and they will come down. In the final rule, they came down a lot, and I used the draft rule data. In the final rule, we are actually using even better data and better claims. I think some of the drug prices will go down and others will go up, so there will be some significant changes.

Last year, the reason I put this chart up is this does not just cost the taxpayers $1 billion. If you look at what we paid on that chart—and you probably cannot read it too well from that distance and I apologize—what you will see is that for some drugs, we will overpay a lot. I will just give you an example: Retuxin last year. When we paid at 95 percent of AWP, we paid $372. This year, when we are using actual hospital claims to pay it, the price is dropping by 20 percent.

Each of the first four drugs on the chart are cancer drugs. As you go down the line, you will find that when you switch from 95 per-

cent of AWP, which we paid in the outpatient setting, to real prices that hospitals pay, you frequently end up with 75 or 80 percent of the AWP. So obviously for taxpayers, paying that lower rate is the right thing to do.

What a lot of people do not realize is the hospital outpatient pot is a finite, roughly $17-billion pot. If you switch to the next chart, I think what you will find is that in addition to paying too much, when we have to put more money into overpaying for drugs, and it is somewhat similar but different for devices, you also have to take money out of basic services. So last year, for instance, the payment in an outpatient setting for colorectal colonoscopies dropped 16.3 percent. For mammographies, it went down 13.2 percent. For emergency room (ER) level visits, the mid-level ER visits, it went down 3.7 percent. When you take out overpayments for drugs you free up money to go back into the base services because it is a finite pot. If we are paying too much for drugs, we are not necessarily just paying too much from taxpayers. We are also taking resources out of other areas for critical services, like colonoscopies, mammographies, and ER visits.

So this year, we found that we took a lot of money out of the payments, and we had overpaid for AWP. We now have 60 million claims, in the final outpatient rule. We are going to take down a lot of payments for a lot of drugs to what we think are far more market oriented, far more appropriate levels. What you find is, and these will change in the final rule, but you will find double-digit increases over last year for payments of colonoscopy, double-digit increases for mammographies, and probably close to double-digit increases for the basic emergency room visit. There is also a direct tradeoff between overpaying for drugs and underpaying for basic hospital services that a lot of people do not understand.

So it is not just bad policy for taxpayers to overpay for outpatient drugs, and it does not just have the impact of spending too much taxpayer money. It also has the impact of negatively affecting hospitals on their basic services for critical preventive services and critical things like emergency room visits. I do not think the connection is often made in that regard.

So we are determined for a variety of reasons, mainly so that we do not overpay for drugs, but also to make sure that we have the accurate payment for base physician and hospital services, to fix this policy. I think it is clear on a bipartisan basis that this is bad payment policy. We have an enormous level of bipartisan support to fix it. It is very clear.

We would very, very much like to have Congress fix AWP this year if you can do it before you go. If you cannot, the Administration is committed to fixing it on our own. I will tell you that, just in brief, if Congress does not fix it this year, our plan is to pick one of our 23 contractors—right now, we have 23 contractors that pay—they, each one of them measures AWP on their own, and they decide what AWP is locally. When you do a poll of those contractors, which we have done, you will find that the payments vary massively and their interpretation of the AWP varies massively.

So administratively, our plan immediately would be later this year to pick one contractor—we have a couple that we believe are better than others. We will pick our best of the 23 carriers and tell

them that they are going to be essentially the common price determiner for what is real AWP. We think that would immediately save $100 million a year.

Then our plan would be to go out and do a much more detailed market survey. Most of our carriers are Blue Cross plans. They know what they are paying for people for the same drugs who are under 65. We believe that if we did nothing but identify appropriate market prices, we could probably save as much as $500 million a year.

We think Congress can probably do more if you direct us to do any one of the hybrid approaches that you have, but our view is the number one thing that we should not do is let this go on any longer. It needs to be fixed as soon as it possibly can.

We would be very anxious to work with the Committee and Congress to try to fix this in the next 2 weeks by any one of the approaches that have been suggested. If not, I think the Administration is committed to fixing it on our own administratively during the course of the next 6 months. Thank you, Madam Chair.

[The prepared statement of Mr. Scully follows:]

Statement of the Hon. Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services

Chairman Johnson, Congressman Stark, distinguished Subcommittee Members, thank you for inviting me to discuss Medicare Part B reimbursement for prescription drugs. As you know, prescription drugs have become an increasingly important component of modern health care, particularly for Medicare beneficiaries. The President has taken a number of steps to provide immediate relief to America's seniors and people with disabilities who have high drug spending, and we are continuing to work closely with Congress to strengthen Medicare by including a comprehensive prescription drug benefit. I would like to thank you for your hard work on creating prescription drug legislation. Although we are disappointed that Medicare beneficiaries still do not have comprehensive drug coverage, we remain hopeful that we can continue to work together to enact this crucial benefit as soon as possible.

It is also critically important that we improve the payment system for the small number of outpatient drugs currently covered by Medicare. It is clear that Medicare's payment system for those covered drugs, based on average wholesale price, or "AWP," is seriously flawed. The Medicare program relies on the prices reported by drug manufacturers to set payment rates. We all agree that Medicare should pay appropriately for all the services and treatments covered by Medicare, including the limited drugs that we currently cover. At the same time, we need to be certain that Medicare pays physicians and other providers appropriately for their services when they furnish drugs to beneficiaries. We support fair, competitive payments for Medicare prescription drugs. We understand that the Committee is working on such a proposal and we look forward to working with you.

By law, Medicare does not pay for most outpatient prescription drugs. However, there are some specific exceptions where Medicare covers pharmaceuticals, such as those drugs that are not self-administered and are furnished incident to a physician's covered services. In these cases, the law requires that Medicare pay physicians and other providers based on the lower of the billed charge or 95 percent of the drugs' AWP. Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare bases its drug payments, are vastly higher than the prices drug manufacturers and wholesalers actually charge physicians and providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers are spending far more than the "average" price that we believe the law intended them to pay for these drugs. Some affected physicians and providers have suggested that these Medicare "drug profits" are necessary to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. We believe that finding a way to pay appropriately for both the drugs and the services related to furnishing those drugs is a better approach.

Clearly, Medicare drug pricing is complex. Over the years, numerous legislative efforts have made progress toward developing an effective alternative to AWP.

These efforts have aimed at ensuring that Medicare and its beneficiaries do not pay more than they should for the prescription drugs that Medicare covers, and that physicians and providers are compensated appropriately for their services. We continue to believe that a legislative remedy to this problem would be preferable, and we will work with Congress to implement effective legislation. However, if necessary, we are prepared to build on the strong evidence and best ideas for reform developed in Congress by taking action under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which provided some authority for the Secretary to act after reviewing the General Accounting Office (GAO) report to Congress. Under BIPA, we could move to a market-based system for drugs and adjust payments for services related to furnishing drugs such as practice expenses for oncology administration. As we look to the future, particularly as we add broader prescription drug coverage to Medicare, it is vital that we develop market-based, competitive pricing systems for drugs so that we do not repeat the past mistakes of overpayment. We are committed to working with Congress to amend the current system to make sure that Medicare pays a fair, competitive price for all benefits, including the limited drugs the program now covers.

MEDICARE'S LIMITED DRUG BENEFIT

The Centers for Medicare & Medicaid Services (CMS) pays most of the health care expenses of almost 40 million Medicare beneficiaries. If Congress were creating the Medicare program today, we believe it would certainly include a prescription drug benefit. When the Medicare program was enacted in 1965, however, prescription drugs played a less prominent role in health care than they do today. Although by law Medicare does not generally cover over-the-counter or outpatient prescription drugs, Medicare does cover some drugs, including:

- Drugs that are not self-administered and furnished "incident to" a physician's service, such as prostate cancer drugs;
- Certain self-administered oral cancer and anti-nausea drugs;
- Certain drugs used in conjunction with certain durable medical equipment or infusion devices, (e.g., the albuterol that is put into nebulizers, which are devices used by asthma patients);
- Immunosuppressive drugs, which are used subsequent to organ transplants;
- Clotting factors for beneficiaries with hemophilia;
- Erythropoietin, the drug that constitutes Medicare's largest drug expenditure, is used primarily to treat anemia in end stage renal disease patients and in cancer patients; and
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.

These drugs are typically provided in hospital outpatient settings, dialysis centers, or doctors' offices, and are purchased directly by the physician or physicians and providers. Generally, Medicare does not cover preventive drugs such as vaccines. However, Medicare law provides coverage specifically for certain vaccines, namely influenza, pneumonia, and hepatitis.

By law, Medicare carriers generally pay for these drugs based on either the actual charge or 95 percent of the AWP, whichever is lower. This adds up to more than $5 billion a year for currently covered drugs, approximately 80 percent of which is paid by the Medicare Trust Funds. In general, Medicare beneficiaries must also share in the cost of purchasing these drugs, except for the flu and pneumonia vaccines, through their Part B premiums, the $100 Part B annual deductible, and a 20 percent coinsurance.

MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices that are reported by drug manufacturers and printed in compendia such as the *Red Book*, published by Medical Economics Company, Inc. However, manufacturers and wholesalers are routinely offering physicians and providers competitive discounts that reduce the actual amount the physician or physicians and providers pays for the drugs. These discounts are not reflected in the published price and reduce the amount many physicians and providers actually pay to levels far below those prices published in the *Red Book*. However, Medicare's regulated payment system is tied to the published price of the drugs, precluding the program from obtaining competitive discounts for the drugs it covers. In addition, use of the AWP, as reported by manufacturers to companies that compile such prices, creates a situation where a manufacturer can, for certain drugs, arbitrarily increase the reported AWP and, in turn, offer physicians a deeper "discount." Furthermore, the deep competitive discounts, compared to the reported AWP, offered by drug

manufacturers could give physicians and physicians and providers incentive to use a particular manufacturer's products for Medicare beneficiaries.

To give an example, a recent General Accounting Office report found that Medicare payments in 2001 for Part B-covered outpatient drugs were often much higher than the prices paid by physicians and pharmacy providers. The GAO reported that discounts of 13 to 34 percent off AWP were widely available for many physician-administered drugs. GAO also noted that two other physician-administered drugs had discounts of 65–86 percent.

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of using AWP as the basis for Medicare drug reimbursement. The IG has published numerous reports showing that true competitive market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and other similar publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP (less 5 percent). It is simply unacceptable for Medicare to continue paying for drugs in an outdated, non-competitive way that costs beneficiaries and the program far more than it should.

In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid by physicians and providers. However, these efforts have been unsuccessful. For example, the Agency's proposed June 1991 physician fee schedule included payments based on 85 percent of AWP. The Agency also proposed that certain high volume drugs be reimbursed at levels equal to either the lesser of 85 percent of AWP or the physicians' and providers' estimated acquisition cost. The Agency received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate. Most comments indicated that while many drugs could be purchased for less than 85 percent of AWP, other drugs were not discounted. Other comments suggested that while pharmacies and perhaps large practices could receive substantial discounts on their drug prices, individual physicians could not. As an alternative, beginning with 1992, the Agency established a policy for Medicare to pay either the AWP or the estimated acquisition cost, whichever was less.

Since the estimated acquisition cost approach proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare payments closer to the prices that physicians and providers pay for drugs, Medicare payments for many drugs were still significantly greater than the competitive discounts obtained by physicians. The system still tied Medicare payments to the artificially inflated industry-reported list prices. In fact, in a December 1997 report, the IG found payments based on AWP to be substantially greater than the prices available to the physician community. As an alternative to actual acquisition costs, Congress considered proposals to pay all Medicare drugs at 83 percent of AWP, a compromise between 95 percent of the AWP and the average discount found by the IG.

In May 2000, the Department of Justice (DOJ) and the National Association of Medicaid Fraud Control Units made advertised market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendium owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the physician and provider community, while not reflecting certain other discounts such as rebates, were closer to the actual average wholesale prices for these drugs than the drug manufacturers' reported AWP. In 2000, the Agency sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001, quarterly update for many of these drugs. Due to concerns about Medicare reimbursement for the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time. Anticipating Congressional action that was soon enacted in BIPA, establishing a moratorium on decreases in Medicare drug reimbursement rates, the Agency in December 2000 postponed Medicare carriers' use of the DOJ data while the GAO conducted a study of Medicare drug pricing and related payment issues. BIPA also provided some authority for the Secretary to address AWP after reviewing the GAO's findings.

FLAWS IN AWP THAT AFFECT THE OUTPATIENT RULE

The shortcomings that I've discussed today regarding AWP also affect payment in the outpatient prospective payment system (OPPS). More specifically, it has affected perceptions about the updated payments for OPPS for 2003. In 2000, CMS adopted a prospective payment system for outpatient services delivered by hospitals, which includes the drugs and devices used in a procedure. By law, payments must be based on the relative cost of treatment. The law further requires that CMS must make additional payments, called "pass-through payments," for new drugs and devices. These payments are allowed for two to three years and, for drugs, are calculated to be the difference between the amount in the rate for existing products and the average wholesale price for the new product. The total dollars set aside for these new drugs and devices currently is limited to 2.5 percent of total spending for services under the outpatient prospective payment system. By law, CMS must use AWPs as reported by the manufacturer for these drugs to set payment rates for these drugs and to calculate the amount funded out of the pass-through pool. Using AWPs that overstate the costs of some drugs results in higher "pass-through payments" and makes less money available for other items eligible for pass-through payments.

In 2003, as a result of collection and analysis of nearly 60 million actual hospital claims, we have been able to set payment rates more accurately. As the payments for some procedures go up, payments for other ones go down and vice versa. However, a recent *New York Times* article misrepresented the impact on payments to hospital outpatient departments. Although payments for many items will be lower in 2003, overall Medicare payments to outpatient departments are projected to increase by almost 8 percent, reflecting hospitals' estimated acquisition costs rather than manufacturers' reported wholesale prices for prescription drugs. While proposed rates for many drugs are lower than 2002 rates, 2002 rates were likely greatly overstated in many cases because they were based on overinflated manufacturers' AWPs.

The story is similar with respect to our payments for procedures using pass-through devices. For 2002 rates we used prices reported by manufacturers to set payment rates for these types of procedures. The other hospital costs for the procedure, such as the operating room, supplies, and nursing time, were calculated using the latest available charges from approximately 50 million hospital claims and the latest available cost reports. I'd like to discuss a couple of examples of how payment rates have changed over the past several years for procedures that use pass-through devices. In my first example, payment for the insertion of a cardioverter-defibrillator, a hospital in 2001 received $7,411 for the procedure plus an additional amount for pass-through devices used during the procedure. The additional payment amount for pass-through devices was equal to the hospital's charges for the device(s) reduced to costs using the latest available hospital's cost-to-charge ratio (CCR). For 2002, the estimated cost of the procedure was about $1,500. Using claims and cost report information from hospitals, we would have added another $6,800 for device costs and the total payment would have been about $8,300. However, because we folded in an additional amount based on prices submitted to us by manufacturers, we added another $11,100 to the payment—bringing the total device-related costs to $17,900. Thus, in 2002, a hospital receives about $19,400 plus an additional amount in pass-through payments. For 2003, we have determined that the total payment for the procedure should be about $9,400. This payment reflects the cost of the procedure ($1,550) plus the estimated cost of devices used with the procedure ($7,850). Because pass-through eligibility for the devices that are being used with this procedure will expire January 1, 2003, we have fully incorporated their estimated costs, using hospital claims and the latest available cost reports, into the costs of the procedure. Similarly in my second example, the implantation of a drug infusion device, a hospital in 2001 received $561 plus an additional amount for pass-through devices used during the procedure. The additional payment amount for pass-through devices was equal to the hospital's charges for the device(s) reduced to costs using the latest available hospital's cost-to-charge ratios (CCR).

For 2002, the estimated cost of the procedure was about $940. Using claims information from hospitals we would have added another $3,800 for device costs and the total payment would have been about $4,750. However, because of the fold-in based manufacturers' reported prices, we added another $2,400 to the payment—bringing the total device-related costs to $6,200. Thus in 2002 a hospital receives about $7,150 plus an additional amount in pass-through payments.

As noted in the proposed rule, we estimate that the total payment for the procedure for 2003 should be about $6,660. This payment reflects the estimated cost of the procedure ($1,640) plus the estimated cost of devices used with the procedure ($5,020). Because pass-through eligibility for the devices that are being used with

this procedure will expire January 1, 2003, we have fully incorporated their estimated costs into the procedure.

To the extent that CMS has to overpay for devices, payments for and access to other services for all beneficiaries are reduced. For example, between 2001 and 2002, payment for diagnostic mammography fell 13 percent. Under the proposed 2003 rates, the rationalization of payment for many devices has helped to allow for an 18% increase in diagnostic mammography payments. In the end, from 2000 to 2003, payment rates for most procedures using pass-through devices will have increased steadily and significantly. We shouldn't be allowing artificial prices nor artificial AWPs to undercut access to basic, preventive, and other services for beneficiaries.

CONCLUSION

Medicare beneficiaries rely on prescription drugs to treat a wide variety of chronic and acute conditions. For many seniors, in the traditional fee-for-service plan, the coinsurance that they pay is tied to Medicare's payment rate. We must find a fair way to make sure that Medicare beneficiaries and taxpayers do not pay excessive prices for prescription drugs that are far above the competitive discounts that are widely available today to other Americans. We need to pay appropriately for all Medicare benefits, including the prescription drugs we do cover and the services required to furnish those drugs. We look forward to working with you Mrs. Chairman, this Committee, and the Congress to implement improvements in Medicare's payment policy for currently covered drugs. Thank you for the opportunity to discuss this important topic with you today, and I am happy to answer your questions.

APCs for Basic and Preventive Services

APC	Description	2001 Rate	2002 Rate	Difference in 2001 vs. 2002 NPRM Rate	Proposed 2003 Rate	Difference in 2002 vs. 2003 NPRM Rate
0158	Colorectal Colonoscopy	$400.93	$335.46	−16.3%	$393.19	+17.2%
0271	Mammography	$35.17	$30.54	−13.2%	$35.89	+17.5%
0601	Mid-level clinic visit	$50.24	$48.36	−3.7%	$54.09	+11.9%
0611	Mid-level ER visit	$106.01	$109.95	3.7%	$138.34	+25.8%

Drug APCs for Select Cancer and Other Drugs with Pass-Through Status Set to Expire January 1, 2003

APC	Descriptor	Brand Name	2001 Total Units	2001 Median Hospital Cost Per Unit	2002 Payment Rate (Net of Pro-rata Reduction)	2003 Proposed Payment Per Unit	Percent Difference Between 2002 Payment (net of pro-rata and 2001 median cost)	Percent Change in 2003 Proposed to 2002 Payment Rate (Net of Pro-rata Reduction)
0849	Rituximab cancer treatment	Rituxan	207,331	$310.85	372.38	$296.97	+20%	−20.3%
7046	Doxorubicin hcl liposome inj	Doxil	36,834	$247.41	294.08	$236.12	+19%	−19.7%
0844	Pentostatin injection	Nipent	258	$1,161.78	1355.13	$1,108.83	+17%	−17.0%
0858	Inj cladribine per 1 MG	Leustatin	10,482	$46.18	34.79	$43.69	−25%	25.6%
7042	Capecitabine, oral, 150 mg	Xeloda	204,556	$1.93	2.00	$1.56	+3%	−22.0%
0733	Non esrd Epoetin alpha Inj	Procrit	12,272,503	$10.32	$9.46	$9.88	−8%	+4.5%
0734	Darbepoetin alfa, 1 mcg	Aranesp				$4.74		

Chairman JOHNSON. There are two other issues I wanted to bring up. One is that I do not believe you have the authority, and you indicated that it is not at all clear to you whether you have the authority. I think you have the authority to compete prices. I think at least that may be less difficult. I would worry about your competing prices and changing prices without the authority to take the money saved and use whatever portion the data indicates to reimburse for practice expenses without putting that money into the big pool of practice expense dollars where it would be averaged across every other physician and increase practice expenses for every physician in every discipline and not adequately increase oncologists.

So as you approach this problem, are you looking at defining in the law clearly that the practice expense money used to reimburse for the drugs whose price we are going to cut will stay with the physicians who have those practice expenses, and not allow that money to sink into the general pool from which practice expenses for every other practicing physician affected by Medicare are reimbursed? Do you think that you have the authority, and are you committed to achieving that goal?

Mr. SCULLY. Well, we are certainly committed to achieving the goal. We would certainly like to make the fix in a context where we do not have a negative 4.4-percent pot, first of all. I think it is clearly appropriate to put the practice expense funds back where they are needed, and there may be other categories, but as I said, oncology is probably number one. Other areas we have identified that rely on AWP for margins are hematologists and dialysis facilities. We clearly think that you should put the money back in where there is a problem. I think we are committed to doing that.

It is unclear, and I have spent a lot of time on it, legally whether we—how we can do that. It would be a lot cleaner and a lot better if Congress directed us to do it that way.

Chairman JOHNSON. We will need to direct you to do it that way, but we will also need help on the clarity of the law. We have spent hours and hours on this. It is hard to define those dollars, keep them in the pool that will reimburse the people appropriately, then have our clean savings, and then maintain that after year one.

So this is an issue that if we do not address correctly, it will, without question, close cancer treatment centers across the country. Our hospital-based cancer treatment facilities are not capable of absorbing the number of patients that need attention, nor would they provide access to elderly people who often are not able to drive themselves. So, the access issue is critical. We are blessed to have developed this system that provides greater access to cancer care than any other Nation provides its elderly, or its citizens. So, we want to be sure to do this right. It does need to be done, but it must be done correctly.

Last, in your experience with bidding drug prices, what standards are you finding you will need to include to prevent things like the following? This is an example that comes to me from California, where they have had some experience in this.

We are trying to figure out accurately from publicly available information how they are doing, if it is the right thing.

In the nursing home field, largely based on that report that we did earlier this year, Congress spent $12 billion a year on Medicare nursing homes, and we added $3 billion in temporarily. The Administration had the discretion to continue $1 billion, and we did that earlier this year. Congress is talking about adding back what are add-ons and the House bill added on about another $1 billion. The Senate did about the same. I think that we are up in the air about that, whether that should be done or not.

Chairman JOHNSON. [Presiding.] Mr. English of Pennsylvania.

Mr. ENGLISH. Thank you, Mr. Scully. At the risk of missing a procedural vote, I do have a question that I wanted to pose to you.

A lot of the discussion about AWP reform is focused on cancer treatments and oncologists, which is one of my areas of interest. Is it not true that there are also some other types of non-cancer therapies that should be included in discussions to ensure that all patients continue to have access to medically necessary therapies? Can you tell me the other types of health care providers, disease states, and drug therapies we should be keeping in mind as we design policies to ensure patient access, and what other types should we be taking into account?

Mr. SCULLY. I think there are a lot of different provider areas that may have small impacts from AWP, and we are certainly willing to work with the Committee to identify those. I think the big dollars are largely in oncology, probably the second biggest is in dialysis facilities who also rely on margins from AWP, and hematologists, the third. I think almost every physician, to some degree, that administers drugs probably has some beneficial cost-shifting benefit from AWP. I think those are the three big areas.

Mr. ENGLISH. My impression is that there are some others that would also be impacted by AWP, including osteoarthritis, rheumatoid arthritis, multiple sclerosis (MS), acquired immune deficiency syndrome (AIDS), and anemia. Have you solicited input from any non-cancer physician provider groups about these issues?

Mr. SCULLY. We have, and I think some of the ones you mentioned, clotting factors is one very large one. I mean, we are more than happy to meet with any of them and discuss any appropriate data they have.

Mr. ENGLISH. Very good. Thank you, and I appreciate your participation today. I also want to thank you again for coming to Northwestern Pennsylvania to help us with some of the reimbursement reform issues and hope to be able to host you there again.

Mr. SCULLY. I am happy to do it. Thanks.

Chairman JOHNSON. Thank you, Mr. Scully. I would hope that as you look at some of these other areas, that you also give some attention to the issue of respiratory therapists. The role that respiratory therapists play in home care is something we need to better understand in making these reimbursement decisions.

Also, I would like to comment for the record that I am concerned about your references to the GAO study and their $49 million. Having spoken with them at great length about their study, they also would acknowledge that their sample of oncologists was very small and that it under-represented the office practice delivery of chemo-